

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ICU MEDICAL, INC., :
: Plaintiff, :
: v. : Civil Action No. 07-468-JJF
: RYMED TECHNOLOGIES, INC., :
: Defendant. :

James Pooley, Esquire; Kimberly N. Van Voorhis, Esquire; Sunil Kulkarni, Esquire; Marc David Peters, Esquire; Diana Luo, Esquire; Katharine Nolan-Stevaux, Esquire; Daniel Wan, Esquire; and Daniel Zlatnik, Esquire of MORRISON & FOERSTER, LLP, Palo Alto, California.

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MEMORANDUM OPINION

December 16, 2009
Wilmington, Delaware

Joseph J. Farnan Jr.
Farnan, District Judge.

Presently before the Court is Defendant RyMed Technologies, Inc.'s Motion To Modify Scheduling Order And For Leave To File Second Amended Answer To ICU Medical, Inc.'s Complaint For Patent Infringement, Defenses, And Counter-Plaintiff RyMed's Counterclaims (D.I. 192). Also before the Court is Plaintiff ICU Medical, Inc.'s Motion For Leave To File Sur-Reply (D.I. 220). For the reasons discussed, Defendant's Motion will be granted. Plaintiff's Motion will also be granted.¹

I. Background

This is a patent infringement case brought by Plaintiff ICU Medical, Inc. ("Plaintiff") against RyMed Technologies, Inc. ("Defendant") alleging infringement of United States Patent Nos. 5,865,866 (the "'866 Patent"); 5,873,862 (the "'862 Patent"); 5,928,204 (the "'204 Patent"); and 6,572,592 (the "'592 Patent") (collectively, "the patents-in-suit"). The patents-in-suit relate to needless intravenous medical connector valves.

On December 29, 2008, the Court issued a Scheduling Order (D.I. 74) directing the parties to file amendments to pleadings by April 16, 2009 and calling for discovery to end on June 26, 2009. On April 16, 2009, the parties filed a Stipulation And Order For Amending Answer, Defenses And Counterclaims (D.I. 86) granting Defendant leave to amend its original Answer.

¹Although Defendant "oppose[s] the content of the proposed Sur-Reply," Defendant does not oppose Plaintiff's Motion For Leave To File Sur-Reply. (D.I. 221, at 1.)

Accordingly, Defendant filed an Amended Answer (D.I. 87) adding an Eighth Affirmative Defense, alleging unenforceability of the '204 Patent due to patent misuse, and a Ninth Affirmative Defense, alleging unenforceability of the '592 Patent due to inequitable conduct. Defendant filed the instant Motion To Modify Scheduling Order And For Leave To File Second Amended Answer To ICU Medical, Inc.'s Complaint For Patent Infringement, Defenses, And Counter-Plaintiff RyMed's Counterclaims ("Motion To Amend") on June 30, 2009, after the deadline for filing amended pleadings had passed. Plaintiff filed its Motion For Leave To File Sur-Reply on August 14, 2009.

II. Parties' Contentions

By its Motion To Amend, Defendant seeks to add a Tenth Affirmative Defense, which alleges that the patents-in-suit are unenforceable due to inequitable conduct. The proposed Tenth Affirmative Defense alleges that Mr. Jean M. Bonaldo ("Mr. Bonaldo") conceived of a needless intravenous connector which was prior art to the patents-in-suit, that Dr. George Lopez ("Dr. Lopez") failed to disclose Mr. Bonaldo as an inventor or co-inventor, and that MSSRS. Phil Mayer,² James Duffield, George Kipe, and Dennis Bui (collectively, the "Alleged Contributors") made key contributions to the inventions claimed in the patents-

²Defendant spells Mr. Mayer's name as "Mr. Myer" in their Motion, but the correct spelling is apparently "Mayer." (D.I.212, at 1.)

in-suit. (D.I. 194, Ex. 1.) Defendant contends that "good cause" exists under Rule 16(b) because Defendant sought leave to file its proposed Second Amended Answer as soon as reasonably possible after discovering the facts necessary to satisfy the pleading standard of Rule 9(b) for inequitable conduct claims. (D.I. 193, at 8-9.) Defendant further contends that its Motion To Amend is proper under Rule 15(a) because it was sought without undue delay, it will not prejudice Plaintiff, and it is sufficiently pled. (*Id.* at 9.) Specifically, Defendant contends that it has diligently pursued discovery since learning of information giving rise to the proposed inequitable conduct claim, that the facts and conduct alleged in the Tenth Affirmative Defense have been known to ICU, and that no additional discovery would be required by either party. (*Id.* at 10.)

In response, Plaintiff contends that Defendant failed to diligently pursue its inequitable conduct claim, and accordingly, that Defendant lacks good cause to amend the Scheduling Order to file its Second Amended Answer. (D.I. 212, at 4.) Specifically, Plaintiff contends that Defendant has had information about alleged joint inventor Mr. Bonaldo since 2008, and that Defendant had information about the alleged roles played by the Alleged Contributors in the patented invention since February 24, 2009 (when Plaintiff produced Dr. Lopez's deposition transcript from

the ICU v. B. Braun case). (Id. at 3.) With respect to Rule 15(a), Plaintiff contests Defendant's assertion that no further discovery would need to be taken, and thus, contends that Plaintiff's Second Amended Answer would cause undue prejudice. (Id. at 8.) Further, Plaintiff contends that the inequitable conduct claim pled in the Second Amended Answer is futile because "it relies on labels only, asserts a conclusory allegation of co-inventorship, and does not assert facts that could support a finding of inequitable conduct." (Id. at 10.)

III. Legal Standard

"After amending once or after an answer has been filed, the plaintiff may amend only with leave of the court or the written consent of the opposing party." Shane v. Fauver, 213 F.3d 113, 115 (3d Cir. 2000) (citing Fed. R. Civ. P. 15(a)). The district court has discretion in granting a motion to amend, Foman v. Davis, 371 U.S. 178, 182 (1962), and "the court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). The Third Circuit has adopted a liberal policy favoring the amendment of pleadings to ensure that claims are decided on the merits rather than on technicalities. Dole v. Arco Chem. Co., 921 F.2d 484, 487 (3d Cir. 1990). Amendment should ordinarily be permitted absent a showing of "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendment previously allowed, undue prejudice to

the opposing party by virtue of the allowance of the amendment, futility of the amendment, etc." Foman, 371 U.S. at 182.

If a party moves for leave to amend the pleadings after a deadline imposed by a Scheduling Order, Rule 16 of the Federal Rules of Civil Procedure is also implicated. Pursuant to Rule 16(b), "a schedule may be modified only for good cause and with the judge's consent." Fed. R. Civ. P. 16(b)(4). After a pleading deadline has passed, the Third Circuit requires a showing of good cause in order to amend. See E. Minerals & Chems. Co. v. Mahan, 225 F.3d 330, 340 (3d Cir. 2000) (affirming district court's denial of motion for leave to amend because no showing of good cause to modify scheduling order was made); see also Dimensional Commc'ns, Inc. v. OZ Optics, Ltd., 148 Fed. Appx. 82, 85 (3d Cir. 2005) (citing E. Minerals to disagree with assertion that Third Circuit had not adopted the good cause requirement when ruling on motions to amend a pleading after a scheduling order deadline has passed). "Good cause" exists when the Schedule cannot reasonably be met despite the diligence of the party seeking the extension. Fed. R. Civ. P 16(b)(4) Advisory Committee's Notes (1983 amendments). "In contrast to Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party." Roquette Freres v. SPI Pharma, Inc., C.A. No. 06-540-GMS, 2009 WL 1444835, at *4 (D. Del. May 21, 2009).

IV. Discussion

A. Rule 16(b)

The Court concludes that Defendant has demonstrated good cause to amend its Answer as required by Rule 16(b). Defendant's proposed Second Amended Answer pleads a new legal theory-inequitable conduct- based on new set of facts obtained and confirmed during discovery which took place after the Scheduling Order's deadline for amended pleadings. Rule 9(b) requires that claims of inequitable conduct in patent cases be pled with particularity. See Enzo Life Sci., Inc. v. Digene Corp., 270 F. Supp. 2d 484, 487 (D. Del. 2003). Where inequitable conduct claims are made, the pleading party is "possibly required to confirm the factual allegations through discovery." See id. at 489; see also Roquette Freres, 2009 WL 1444835, at *5 (finding it "appropriate" for defendant to confirm proposed inequitable conduct allegations through discovery).

Plaintiff contends that had Defendant followed through on information produced, Defendant could have amended its Answer before the deadline. (D.I. 212, at 1.) Namely, Plaintiff points to produced documents revealing Plaintiff's previous interactions with Mr. Bonaldo, as well as other patents in which Mr. Bonaldo was cited as prior art, and a deposition transcript produced in February 2009 in which Dr. Lopez discussed the role of the Alleged Contributors. (Id. at 3-7.) While some references to Mr.

Bonaldo's invention and the inventive contributions of others were made within the course of discovery, the Court finds that Defendants could not have gathered sufficient information from these sources to plead an inequitable conduct claim with particularity. The Court further finds that Defendant acted diligently in pursuing the inequitable conduct claim and in discovering facts necessary to plead with particularity because: 1) Defendant issued subpoenas to Mr. Bonaldo on June 5, 2009; 2) Mr. Bonaldo produced responsive documents on June 15, 2009; 3) Mr. Bonaldo was deposed on June 16 and 26, 2009; 4) Dr. Lopez was deposed on June 23 and 24, 2009; and 5) Defendant filed the instant Motion To Amend on June 30, 2009. Accordingly, the good cause requirement of Rule 16(b) is satisfied.

B. Rule 15(a)

Turning to Rule 15(a), the Court concludes that Plaintiff will not be unduly prejudiced if Defendants are granted leave to amend, and that the inequitable conduct claim contained in the Tenth Affirmative Defense of the Second Amended Answer is not futile. In order to prove undue prejudice, the non-movant "must show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered . . . had the amendments been timely." Bechtel v. Robinson, 886 F.2d 644, 652 (3d Cir. 1989) (citing Heyl & Patterson Int'l, Inc. v. F.D. Rich Hous. of V.I., Inc., 663 F.2d

419, 426 (3d Cir. 1981)). Plaintiff's arguments regarding prejudice relate to the fact that discovery is now closed, and that it has not conducted discovery from the Alleged Contributors³ and that it has not had an opportunity to adequately cross-examine Mr. Bonaldo. (D.I. 212, at 8.)

The Court concludes that any prejudice to Plaintiff which would exist as a result of permitting Defendant to add its inequitable conduct claim is not undue, and therefore, does not warrant denial of leave to amend. Plaintiff was able to depose Mr. Bonaldo, and it presumably possesses extensive information about its previous interactions with him. Plaintiff also deposed the inventor of their patents-in-suit, Dr. Lopez. Further, as a basis for asserting that Defendant lacked good cause, Plaintiffs pointed to Dr. Lopez's deposition testimony in the ICU v. B. Braun case, in which Dr. Lopez "explained the [Alleged Contributor]s' roles in reducing his inventions to practice and explicitly rejected the idea that these individuals provided the concept for his inventions." (Id. at 2.) Thus, Plaintiff was previously aware of the issues surrounding alleged contributions to the inventions claimed by the patents-in-suit.

Amendment of a complaint is futile if it fails to state a claim upon which relief can be granted. In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d. Cir. 1997) (citing

³Mr. Mayer is now deceased. (D.I. 212, at 8.)

Glassman v. Computervision Corp., 90 F.3d 617, 623 (1st Cir. 1996)). Rule 9(b) requires that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 9(b). With respect to allegations of inequitable conduct before the Patent and Trademark Office during a patent prosecution, “pleadings that disclose the name of the [allegedly withheld] relevant prior art and disclose the alleged fraud fulfill the requirements of Rule 9(b).” EMC Corp. v. Storage Tech. Corp., 921 F. Supp. 1261, 1263 (D. Del. 1996).

Defendants have disclosed the allegedly withheld relevant prior art- a needless intravenous connector conceived of by Mr. Bonaldo and patented as U.S. Patent No. 5,273,533. (D.I. 194, Ex. 1.) In addition, Defendants disclose that the alleged fraud is a knowing and willful failure by Plaintiff and Dr. Lopez to disclose Mr. Bonaldo as an inventor or co-inventor of the patents-in-suit. (Id.) Accordingly, the Court concludes that inequitable conduct has been pled with requisite particularity, and that the claim is not futile because the factual allegations of are enough to raise a right to relief above the speculative level, and the claim is plausible on its face.

V. Conclusion

For the reasons discussed, Defendant RyMed Technologies, Inc.’s Motion To Modify Scheduling Order And For Leave To File

Second Amended Answer To ICU Medical, Inc.'s Complaint For Patent Infringement, Defenses, And Counter-Plaintiff RyMed's Counterclaims will be granted. Plaintiff ICU Medical, Inc.'s Motion For Leave To File Sur-Reply will also be granted.

An appropriate Order will be entered.